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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,075	03/30/2004	Yoshinori Sekiguchi	Q74855	3021

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EXAMINER	
JAISLE, CECILIA M	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,075	SEKIGUCHI ET AL.	
	Examiner	Art Unit	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,52-96,99-101,103-106 and 112* is/are pending in the application.

4a) Of the above claim(s) *52-56,59-62,65-67,69-71,73 and 74* is/are withdrawn from consideration.

5)☒ Claim(s) *2,57,58,63,64,68,72,75-96 and 99-101* is/are allowed.

6)☒ Claim(s) *103-106 and 112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Restriction

Applicant's election of Group III, drawn to compounds of formula I wherein Q is formula IV (pyrimidine), and pharmaceutical compositions thereof, classified in classes 514 and 544, various subclasses depending on substituents, in the reply filed on Oct. 23, 2006 is acknowledged. Applicant's further election of the species of Example 3398, 3-chloro-N-[cis-4-(4-dimethylamino-5-methyl-pyrimidin-2-ylamino)-cyclohexyl]-4-fluoro-benzamide methanesulfonic acid, in the further reply filed on Mar. 13, 2007 is also acknowledged. Claims 2, 57, 58, 63, 64, 68, 72, 75-96, 99-101 and 103 read on the elected species, and these claims are under examination only to the extent that they are patentably indistinct from the elected species. Claims 52-56, 59-62, 65-67, 69-71, 73, 74, 104-106 and 112 are withdrawn as non-elected.

Rejoinder

Claims 2, 57, 58, 63, 64, 68, 72, 75-96, 99-101 and 103 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 104-106 and 112, directed to the process of using and making, respectively, the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 52-56, 59-62, 65-67, 69-71, 73 and 74, directed to the inventions of

Groups I, II and IV do not require all the limitations of an allowable product claim, and have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement in Groups III between compounds, compositions and methods of use as set forth in the Office action mailed on Sep. 22, 2006 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Rejections Under 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 104-106 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for prophylaxis or treatment of improving memory function, sleeping and arousal, anxiety, depression, mood disorders, seizure, obesity, diabetes, appetite and eating disorders, cardiovascular disease,

hypertension, dyslipidemia, myocardial infarction, binge eating disorders including bulimia, anorexia, mental disorders including manic depression, schizophrenia, delirium, dementia, stress, cognitive disorders, attention deficit disorder, substance abuse disorders and dyskinesias including Parkinson's disease, epilepsy, and addiction (claims 104-106). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed scope includes disorders that are not clearly defined, so that it is not possible to determine the disorders intended. For example, “depression” cannot be clearly distinguished from and/or overlaps “mood disorders,” “mental disorders;” “schizophrenia” cannot be clearly distinguished from and/or overlaps “mood disorders”; “appetite and eating disorders” cannot be clearly distinguished from and/or overlap “binge eating disorders including bulimia, anorexia,” “substance abuse disorders”; “cardiovascular disease” cannot be clearly distinguished from and/or overlaps “hypertension, dyslipidemia, myocardial infarction”; “cognitive disorders” cannot be clearly distinguished from and/or overlap “attention deficit disorder,” “mental disorders”; “addiction” cannot be clearly distinguished from and/or overlaps “appetite and eating disorders,” “binge eating disorders including bulimia, anorexia,” “substance abuse disorders”; *inter alia*.

Due to inaccurate punctuation, it is not possible to determine the illustrative conditions intended after the term “including.” In addition, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation

(in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "including " and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 104 recites the broad recitations “binge eating disorders,” “mental disorders,” “attention deficit disorder,” and the claim also recites narrower statements of each disorder.

The term “prophylaxis” refers to any agent or procedure whose purpose is to prevent, rather than treat or cure a disease. Roughly, prophylactic measures are divided between *primary* prophylaxis (to prevent the development of a disease) and *secondary* prophylaxis (whereby the disease has already developed and the patient is protected against worsening of this process). The claims fail to specify if the present methods are intended to have a *primary* or *secondary* prophylactic effect on the conditions enumerated above, how patients in need such prophylactic effect are identified, how such prophylactic effect will be obtained and how it will be recognized. Many if not most disorders said to be prevented by the claimed methods are not known as preventable. At

present no known drug can successfully prevent many of these disorders. Substantiation of utility and its scope is required when utility is "speculative," "sufficiently unusual" or not provided. See *Ex parte Jovanovics, et al.*, 211 USPQ 907, 909 (BPAI 1981). Also, note *Hoffman v. Klaus*, 9 USPQ2d 1657 (BPAI 1988) and *Ex parte Powers*, 220 USPQ 924 (BPAI 1982) regarding types of testing needed to support *in vivo* uses.

Applicants' attention is drawn to the Revised Interim Utility and Written Description Guidelines, at 66 FR 1092-1099 (2001), emphasizing that "a claimed invention must have a specific and substantial utility." See also MPEP 2163, *et. seq*. This application's disclosure is insufficient to enable the instantly claimed methods. The state of the art indicates the requirement for undue experimentation.

Many factors require consideration when determining whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue." MPEP 2164.01(a). These factors include: (1) the claim breadth; (2) the nature of the invention; (3) the state of the prior art; (4) the level of predictability in the art; (5) the amount of direction provided by the inventor; (6) the presence of working examples; and (7) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)(reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). See also *In re Goodman* 29 USPQ2d 2010, 2013 (Fed. Cir. 1993). Application of these factors to the present application supports the determination that the present disclosure fails to satisfy the enablement requirement:

(1) Breadth of claims.

(a) Scope of the methods. The method claims cover the use of substituted pyrimidines and their pharmaceutically acceptable salts.

(b) Scope of the disorders covered. The scope of the disorders said to be treated and prevented by the claimed methods are highlighted above.

The claims encompass all disorders, including ones yet to be determined, embraced by various insufficiently defined terms used to identify the intended disorders. At present no known drug can successfully inhibit or prevent the course of many of these disorders.

There are several forms of **depression**.

- **Major depressive disorder** (major depression) is characterized by a combination of symptoms that interfere with a person's ability to work, sleep, study, eat, and enjoy once–pleasurable activities. Major depression is disabling and prevents a person from functioning normally. An episode of major depression may occur only once in a person's lifetime, but more often, it recurs throughout a person's life.
- **Dysthymic disorder** (dysthymia) is characterized by long-term but less severe symptoms that may not disable a person but can prevent one from functioning normally or feeling well. People with dysthymia may also experience one or more episodes of major depression during their lifetimes.

- Some forms of depressive disorder exhibit different characteristics than those described above, or develop under unique circumstances. Not all scientists agree on how to characterize and define the following forms of depression.
- **Psychotic depression** occurs when a severe depressive illness is accompanied by some form of psychosis, e.g., a break with reality, hallucinations and delusions.
- **Postpartum depression** is diagnosed if a new mother develops a major depressive episode within one month after delivery. The estimate is that 10 to 15 percent of women experience postpartum depression after giving birth.
- **Seasonal affective disorder (SAD)** is characterized by onset of a depressive illness during winter months, when there is less natural sunlight. Depression generally lifts during spring and summer. SAD may be effectively treated with light therapy, but nearly half of those with SAD do not respond to light therapy alone. Antidepressant medication and psychotherapy can reduce SAD symptoms, either alone or in combination with light therapy.
- **Bipolar disorder**, also called **manic-depressive illness**, is less common than depression or dysthymia. It is characterized by cycling mood changes- from extreme highs (e.g., mania) to extreme lows (e.g., depression).

Appetite and eating disorders, binge eating disorders including bulimia, anorexia are complex, marked by extremes. Despite scientific research to understand them, their biological, behavioral and social underpinnings remain

elusive. The main eating disorders include anorexia nervosa, bulimia nervosa and binge-eating disorder. Another category is "eating disorders not otherwise specified" (EDNOS), which includes several eating disorder variations.

Cognitive disorders do not have a clear definition and can include delirium, dementia, amnesic disorders, dementia associated with alcoholism, dementia of the Alzheimer type, as well as many others.

Schizophrenia has no prevention or cure, but medication has been shown to be effective against psychotic symptoms.

It is unclear whether **arousal** is intended to refer to awakening or sexual arousal.

The other disorders/diseases listed by the claims similarly construe a variety of unrelated conditions having various unrelated causes and treatments, and which may or may not be susceptible to prophylaxis.

(2) The nature of the invention and predictability in the art: Therapeutic use of substituted pyrimidines and salts in preventing and treating disorders recited above. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved" and physiological activity is generally considered to be an unpredictable factor. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

(3) Direction or Guidance: That provided is very limited. The dosage range information is meager; it would require extensive experimentation to determine a specific dosage for a specific recited disorder, mode of administration and therapeutic regimen, for treatment or for prevention. Dosage is generic; the same for many disorders the specification covers. No specific direction or guidance gives a regimen or dosage

effective specific for a single disease. No dosage or therapeutic regimen is present to direct the skilled artisan to protect a potential host from all named disorders. No guidance is offered as to how to identify a subject susceptible to any of the conditions/disorders recited so that prophylactic treatment may be administered.

(4) State of the Prior Art: The methods are disclosed as MCH receptor antagonists.

Shi, Peptides, Volume 25, Issue 10, Oct. 2004, Pages 1605-1611, cautions:

> However, major questions remain about the mechanisms regarding the regulatory roles of MCH in energy homeostasis and neurological functions. For example, significant differences exist between the MCH and MCHR1 knockout mice as to the causes for weight loss. There are also differences between human and rodents in MCH function as evidenced by the lack of a functional MCHR2 receptor in mice and rats. Thus, precautions have to be taken when interpreting data from rodents in relation to human physiology of MCH mediated events, such as changes in energy expenditure and behaviors observed in mice with targeted deletion of MCHR1 or mice treated with antagonist compounds. Furthermore, due to a lack of an animal model, it remains a challenge to investigate the physiological function of MCHR2 in humans. Finally, the wide distribution of MCHR1 expressing neurons in the brain suggests multifunctional roles for MCH in regulating brain activity, such as behavior, olfaction, memory, and emotions, which remain to be investigated in future studies.

Schwartz, et al., *Nature Medicine* **8**, 779 - 781 (2002), similarly urges caution and the need for further study:

> Of obvious concern is the possibility that MCH receptor blockade will have adverse effects in humans not detected in animal studies. Indeed, the hypothesis that MCH participates in regulation of food intake, mood or anxiety in humans remains untested, so the therapeutic potential of MCH-receptor antagonists in human obesity or psychiatric disorders is difficult to estimate. These concerns are allayed to some extent by evidence that key molecules governing energy homeostasis are conserved across mammalian species, but the hard work of translating basic findings into clinical practice still lies ahead.

Hu, et al., J. Pharmacol. & Experim. Therap., 324:206-213, 2008, reports the need to get MCH antagonists into the brain:

> Our findings support the concept that the MCH1R is a good target for obesity therapy. Blockade of the receptor in mouse and rat obesity models lead to significant weight loss. Our studies clearly indicate that brain access is critical for efficacy of small-molecule MCH1R antagonists. The need to get these small-molecule antagonists into the brain may be one of the reasons that MCH antagonists have yet to reach clinical studies. Given the importance of finding efficacious pharmacological therapeutics for obesity, it is likely that MCH antagonists will one day be part of the clinical cadre of therapies.
>
> Sailer, et al., Proc Natl Acad Sci U S A. 2001 June 19; 98(13): 7564–7569,

recommends the need for further research:

> [W]e present here the discovery of human MCH-2R as a second G protein-coupled receptor for MCH. Considering the wide range of possible physiological activities attributed to MCH and the selective expression of MCH-2R in human brain, especially in the hypothalamus, it will be of interest to define the role of this receptor in human physiology.
>
> Unmehopa, et al., J. Clin. Endocrin. & Metab., Vol. 90, #4, 2412-2419, 2005,

urges further study:

> MCH1R staining was found in cell bodies most pronounced in the INF/ME region of the human hypothalamus. The up-regulation of the number of MCH1R-containing neurons in this region in cachexia is consistent with a function of MCH as an orexigenic neuropeptide in the human brain. The presence of MCH1R-expressing neurons and fibers in multiple other sites points to additional functions of the MCH/MCH1R system in humans, including in the stress response and depression, a possibility that warrants further studies.

The ability of the claimed methods to prevent and treat all disorders asserted above remains open to proof. The skilled person in this art would encounter the need for undue experimentation.

(5) Working Examples: No disclosure correlates *in vitro* results to *in vivo* treatment and inhibition of all disorders construed by the claims. The specification prophesies that

the methods will treat and prevent all disorders mentioned above, but no working examples actually show treatment or prevention of even a single disorder.

The specification states that the methods treat and prevent all recited disorders, for which Applicants provide no competent evidence. Applicants have not provided competent evidence of known tests highly predictive for all disorders embraced by the claim language for the intended host. Pharmacological activity in general is unpredictable. In applications involving physiological activity, such as the present,

> "The first paragraph of 35 U.S.C. 112 effectively requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."

Plant Genetic Syst. v. DeKalb Genetics, 65 USPQ2d 1452, 1456 (Fed. Cir. 2003). "[T]he scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 166 USPQ 18 (CCPA 1970).

(6) Skill of those in the art: See the discussion above of Shi, Schwartz, Hu, Sailer and Unmehopa. The state of the art supports that successful treatment and prevention of all disorders recited is a subject for further investigation.

(7) The quantity of experimentation needed: Based on the disclosure content, to use the invention would place an undue burden on one skilled in the pharmaceutical arts, since the disclosure gives the skilled artisan inadequate guidance regarding pharmaceutical use, for the reasons stated above.

The discussion of the above factors demonstrates that the present application sufficiently lacks enablement of the present claims. In view of the breath of the claims,

the pharmaceutical nature of the invention, the unpredictability of relationship between 5-HT2 receptor antagonist activity and treatment and prevention of all disorders, one of ordinary skill in this art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states,

> A conclusion of lack of enablement means that, based on the evidence regarding each of the above [Wand] factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed.Cir. 1993).

Sitrick v. Dreamworks LLC, 85 USPQ2d 1826, 1830 (Fed. Cir. 2008) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable all of the embodiments. "Because the asserted claims are broad enough to cover both [embodiments], the [specification] must enable both embodiments." Here, the claims at issue cover many embodiments and do not enable them.

Automotive Tech. Int'l. v. BMW of N. America, Inc., 84 USPQ2d 1108, 1116 (Fed. Cir. 2007) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable one of the embodiments. "Thus, in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both [embodiments], which the specification fails to do." Here, the claims at issue cover many embodiments and do not enable them.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 103-106 and 112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- These claims are incomplete; they depend on cancelled claims 97-98 and 102.
- The scope of claims 104-106 includes disorders that are not clearly defined, so that it is not possible to determine the disorders intended. For example, "depression" cannot be clearly distinguished from and/or overlaps "mood disorders," "mental disorders;" "schizophrenia" cannot be clearly distinguished from and/or overlaps "mood disorders"; "appetite and eating disorders" cannot be clearly distinguished from and/or overlap "binge eating disorders including bulimia, anorexia," "substance abuse disorders"; "cardiovascular disease" cannot be clearly distinguished from and/or overlaps "hypertension, dyslipidemia, myocardial infarction"; "cognitive disorders" cannot be clearly distinguished from and/or overlap "attention deficit disorder," "mental disorders"; "addiction" can-not be clearly distinguished from and/or overlaps "appetite and eating disorders," "binge eating disorders including bulimia, anorexia," "substance abuse disorders"; *inter alia*.
- Due to inaccurate punctuation in claims 104-106, it is not possible to determine the illustrative conditions intended after the term "including." In addition, a broad range or limitation together with a narrow range or limitation falling within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth metes and bounds of patent protection desired. MPEP 2173.05(c). Note the explanation given by Board of Patent Appeals and

Interferences (BPAI) in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (BPAI 1989), where broad language is followed by "such as " and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required claim feature. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 104 recites the broad recitations “binge eating disorders,” “mental disorders,” “attention deficit disorder,” and the claim also recites narrower statements of each disorder.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

Cecilia M. Jaisle, J.D.
9/18/2008